pending in this application and neglects to list claim 155 as pending in this application. A courtesy copy of the pending claims is included herewith as Exhibit A

Applicants note with appreciation that the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement has been withdrawn. The remarks made herein narrow the issues on appeal and are designed to place the case in condition for allowance. As such, Applicants respectfully request that the remarks made herein be entered and fully considered.

1. FORMAL DRAWINGS

The Notice of Draftsperson's Patent Drawing Review attached to the Office Action, mailed October 21, 2002, states that the drawings filed on June 30, 2000 are objected to by the Draftsperson under 37 C.F.R. § 1.84(l) because the lines, numbers and letters in Figures 1A-11 are not uniformly thick and well defined, clean, durable and black. Applicants filed on June 18, 2002 a Transmittal of Formal Drawings and formal drawings (40 sheets, representing Figures 1-27). In order to confirm that the United States Patent and Trademark Office received the formal drawings filed on June 18, 2002 and to find out if those drawings obviated the Draftsperson's objection to Figures 1A-11, attorneys for Applicants contacted the Draftsperson. The Draftsperson reviewed the formal drawings and sent a facsimile (a copy of which is attached hereto as Exhibit B) stating that the objection to the formal drawings was waived.

2. THE REJECTION UNDER 35 U.S.C. .§ 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

Claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 231, 233-235, 237, 238, 240, 242, 245-252, 254 and 256-264 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner states that Applicants' arguments presented in the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002 ("Amendment"), were fully considered but were not persuasive. The Examiner does not provide any reasons as to why the arguments presented by Applicants in the Amendment were not persuasive. The Examiner merely states that Applicants traversed the written description rejection on the grounds that methods for generating antibodies that comprise one defined CDR, wherein the antibodies bind specifically to a particular antigen were well-known in the art as of the effective filing date. Applicants respectfully point out that additional arguments were presented by

Applicants in the Amendment regarding the written description rejection. Accordingly, in the absence reasons for maintaining the rejection, Applicants have assumed that the rejections are maintained for the reasons presented in the Office Action, mailed December 18, 2001. For the reasons detailed below, Applicants respectfully assert that the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description support cannot stand and should be withdrawn.

The written description requirement under 35 U.S.C. § 112, first paragraph, is satisfied by describing the claimed invention using such descriptive means as words, structures, diagrams, formulas, etc., that fully set forth the claimed invention. *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1329 (Fed. Cir. 2002); citing *Lockwood v. American Airlines, Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

With respect to claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 231, 233-235, 237, 238, 240, 242, 245-252, 254 and 256-264, the Examiner contends that there is no written description support in the specification for the recited combinations and permutations of complementarity determining regions ("CDRs"). Applicants respectfully assert that there is, indeed, written description support in the specification of the present application for the recited combinations and permutations of CDRs in the pending claims.

The specification of the present application provides adequate written description of antibodies that immunospecifically bind to a human TANGO 268 antigen, said antibodies comprising one or more variable heavy ("VH") CDRs having the amino acid sequence of one or more of the VH CDRs of the scFv clone A10 and/or one or more variable light ("VL") CDRs having the amino acid sequence of one or more VL CDRs of the scFv clone A10. The specification of the present application also provides adequate written description of kits and compositions comprising said antibodies. Further, the specification of the present application provides adequate written description of antibodies that compete with the scFv clone A10 for binding to a human TANGO 268 antigen. The Examiner's attention is directed to Table 7 on page 102 of the specification of the present application for the amino acid sequences of the VH CDRs and VL CDRs of the scFv clone A10. The Examiner's attention is also directed to the ATCC® deposit information for the scFv clone A10 provided on page 147 of the specification of the present application. Applicants respectfully point out that the CDR sequences recited in Table 7 for the scFv clone A10 are encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442 and that one of skill in the art would be able to ascertain the amino acid sequences of the VH CDRs and VL CDRs of the deposited clone using well-known techniques. Further, Applicants respectfully assert that one of skill in the art would

be able to ascertain the various combinations and permutations of the CDRs of the antibodies of the claimed invention based upon the written description in the specification of the present application.

As requested by the Examiner on page 3 of the Office Action, mailed December 18, 2001, Applicants, on pages 11-17 of the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002, set forth page and line numbers in the specification of the present application for specific, detailed support for each claim. The Examiner's attention is directed to pages 11-17 of the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002 for the specific, detailed written description support for each claim.

With respect to claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 233-235, 237, 238, 240, 242, 245-251 and 256-264, the Examiner contends that there is no written description support for these claims since the sequence for all six CDRs are not defined. In particular, the Examiner contends that there is no written description support for the required structural features of the antibodies recited in these claims that would confer the ability to bind to a TANGO 268 antigen. The Examiner contends that the structure of the antigen-binding sites of the antibodies recited in these claims are not conventional in the art and thus, one of skill in the art would not recognize from the disclosure that Applicants were in possession of the genus of an antibody that specifically binds to a TANGO 268 antigen, minimally comprising a CDR encoded by the cDNA insert of the plasmid deposited with the ATCC® as patent deposit Number PTA-2442.

"If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, page 1106, Friday, January 5, 2001.

Applicants respectfully assert that the specification coupled with information well-known in the art as of the effective date of the present application would reasonably convey to one of skill in the art that Applicants were in possession of the antibodies recited in the pending claims. First, contrary to the Examiner's contention, the structure of the antigen-binding sites of the antibodies of the claimed invention are conventional to one of skill in the art. The pending claims are directed to antibodies that immunospecifically bind to a human TANGO 268 antigen, said antibodies comprising antigen-binding sites having the structural characteristics of the various types of antibodies well-known to one of skill in the art including those disclosed in the specification of the present application on page 86, line 35 to page 87, line 8. According to the Synopsis of Application of Written Description Guidelines, at page 59, available at http://www.uspto.gov/web/patents/guides.htm

("Application Guidelines"), "[t]he general knowledge in the art is such that antibodies are structurally well characterized."

Example 16 in the Application Guidelines states that a specification that teaches a novel antigen X, methods of isolating antigen X, a use for an antibody that binds to antigen X, and contemplates but does not teach an example of an antibody capable of binding to an antigen X provides adequate written description for a claim reciting an isolated antibody capable of binding to antigen X. See Application Guidelines at pages 59-60. Unlike this example, pending claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 233-235, 237, 238, 240, 242, 245-251 and 256-264 provide additional information regarding the structure of the antibodies, in particular the structure of the hypervariable regions of the antibodies. More specifically, these claims recite the amino acid sequence of one or more of the CDRs of the antibodies that immunospecifically bind to a human TANGO 268 antigen.

Second, as previously stated in the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002, methods for generating antibodies comprising one defined CDR, wherein the antibodies immunospecifically bind to a particular antigen were well-known in the art as of the effective date of the present application. Applicants direct the Examiner's attention to Jirholt et al., 1998, Gene 215: 471-476 ("Jirholt"), Soderlind et al., 1999, Immunotechnology 4: 279-285 ("Soderlind"), and International Publication No. WO 98/32845 attached to the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002, as Exhibits G-I. Soderlind and International Publication No. WO 98/32845 teach methods of generating antibodies comprising one to six unknown CDRs. In particular, Soderlind and International Publication No. WO 98/32845 teach antibodies comprising one or more defined CDRs with the remaining CDRs being unknown.

Third, as previously stated in the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002, methods for identifying antibodies that immunospecifically bind to a human TANGO 268 antigen are described in the specification of the present application and were well-known as of the effective filing date of the present application. See, page 104, lines 18-29 and page 51, line 1 to page 56, line 22 of the specification of the present application, and Chapter 14 of Harlow et al., eds, 1988, Antibodies A Laboratory Manual, Cold Spring Harbor, New York (Exhibit J of the Amendment Under 37 C.F.R. § 1.111, filed June 18, 2002). Thus, contrary to the Examiner's contention, Applicants respectfully assert that the specification coupled with the state of the art with respect to antibodies would reasonably convey to one of skill in the art that Applicants were in possession of an antibody comprising a CDR having an amino acid sequence of a CDR of the scFv clone A10, wherein the

antibody immunospecifically binds to a human TANGO 268 antigen, as of the effective filing date of the present application.

Even assuming, *arguendo*, the Examiner is not persuaded by Applicants arguments regarding the written description support in the specification for the pending claims that recite antibodies that contain less than six CDRs, Applicants are dumbfounded that the Examiner has rejected claims 231 and 252. Claim 231 is directed to a substantially purified antibody comprising VH CDRs 1-3 and VL CDRs 1-3 of the scFv clone A10, wherein said antibody immunospecifically binds to a human TANGO 268 antigen. Claim 252 is directed to a substantially purified scFv antibody comprising the amino acid sequence encoded by the cDNA insert of the plasmid deposited with the ATCC as patent deposit Number PTA-2442. Written description support in the specification of the present application for claims 231 and 252 can be found at page 95, line 36 to page 96, line 2, page 96, lines 7-10 and page 98, lines 26-27, and at page 95, lines 19-23, respectively. Moreover, as acknowledged by the Examiner on page 6 of the Office Action, mailed December 18, 2001, the antibodies recited in claims 231 and 252 provide sufficient written description of the structure of these antibodies. Accordingly, at a minimum there is adequate written description support for claims 231 and 252 in the specification of the present application.

In view of the foregoing, Applicants respectfully assert that the rejection under 35 U.S.C. § 112, first paragraph, cannot stand and should be withdrawn.

CONCLUSION

Applicants respectfully request entry and consideration of the foregoing remarks. Applicants believe that all of the present claims meet all of the requirements for patentability. Withdrawal of all rejections is requested.

If any issues remain, the Examiner is requested to telephone the undersigned at (212) 790-6431.

Respectfully submitted,

Date: February 21, 2002

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